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Corporation, Novartis Pharma AG and
Novartis International Pharmaceutical Ltd.

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U.S. DISTRICT COURT

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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

----- X
NOVARTIS PHARMACEUTICALS CORPORATION, :
NOVARTIS PHARMA AG, and NOVARTIS :
INTERNATIONAL PHARMACEUTICAL LTD., :
:

Plaintiffs, :
:

v. :
:

TEVA PHARMACEUTICALS USA, INC., :
:

Defendant. :
----- X

CIVIL ACTION NO.:

05-1887(RSH)

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Novartis Pharmaceuticals Corporation, Novartis Pharma AG and Novartis International Pharmaceutical Ltd. (hereinafter collectively "Novartis"), for their Complaint for patent infringement herein against defendant Teva Pharmaceuticals USA, Inc. allege as follows:

PARTIES

1. Plaintiff Novartis Pharmaceuticals Corporation ("NPC") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 59 Route 10, East Hanover, New Jersey 07936.

2. Plaintiff Novartis Pharma AG ("Pharma AG") is a corporation organized and existing under the laws of Switzerland, having an office and place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland.

3. Plaintiff Novartis International Pharmaceuticals Ltd. ("NIP") is a corporation organized and existing under the laws of Bermuda, having an office and place of business at Hurst Holme, 12 Trott Road, Hamilton HM LX, Bermuda.

4. On information and belief, Teva Pharmaceuticals USA, Inc. ("Teva USA") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1090 Horsham Road, P.O. Box 1090, North Wales, Pennsylvania 19454-1090. On information and belief, Teva USA is registered to do business in New Jersey, having appointed a registered agent in New Jersey, and having regular and established places of business at 92 Route 46 East, Elmwood Park, New Jersey 07407, and at 8/10 Gloria Lane, Fairfield, New Jersey 07004.

JURISDICTION AND VENUE

5. This action arises under the patent laws of the United States of America. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

6. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b) and (c), and 28 U.S.C. § 1400(b).

CLAIM FOR PATENT INFRINGEMENT

7. Plaintiff NPC holds an approved new drug application ("NDA") No. 20-363 for Famvir® tablets (125 mg, 250 mg and 500 mg), which tablets contain the active ingredient famciclovir. Famvir® tablets are approved by the United States Food and Drug Administration ("FDA") for the treatment of acute herpes zoster (shingles), the treatment or suppression of recurrent genital herpes in immunocompetent patients and the treatment of recurrent mucocutaneous herpes simplex infections in HIV-infected patients. Famvir® tablets are sold in the United States by Plaintiff NPC.

8. The active ingredient in the Famvir® tablets, famciclovir, is known chemically as 2-[2-(2-amino-9H-purin-9-yl)ethyl]-1,3-propanediol diacetate or 2-amino-9-(4-acetoxy-3-acetoxymethylbut-1-yl)purine.

9. Plaintiff NIP is the owner of United States Patent No. 5,246,937 ("the '937 patent"). The '937 patent was duly and legally issued on September 21, 1993.

10. The '937 patent claims 2-amino-9-(4-acetoxy-3-acetoxymethylbut-1-yl)purine, pharmaceutically acceptable salts thereof, and pharmaceutical compositions

containing them, as well as methods of treating herpesvirus infections. A true copy of the '937 patent is attached hereto as Exhibit A.

11. On information and belief, Teva USA submitted to the FDA an abbreviated new drug application ("ANDA") under the provisions of 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, and sale of famciclovir 125 mg, 250 mg and 500 mg tablets.

12. On information and belief, Teva USA submitted its ANDA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of its famciclovir 125 mg, 250 mg and 500 mg tablets before the expiration of the '937 patent.

13. On information and belief, Teva USA made, and included in its ANDA, a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") that, in its opinion and to the best of its knowledge, the '937 patent is invalid or will not be infringed.

14. The relevant statute (21 U.S.C. § 355(j)(2)(B)(iv)(II)) requires that a notice of the Paragraph IV certification ("Notice Letter") "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)(6)) further require that the detailed statement include "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation."

15. On information and belief, on or about February 22, 2005, Teva USA sent a Notice Letter, purporting to comply with the provisions of 21 U.S.C. § 355(j)(2)(B) and the FDA regulations relating thereto, to Novartis Corporation, Novartis International AG, and Plaintiffs NPC and NIP.

16. In the Notice Letter, Teva USA did not provide the detailed statement required by, and therefore failed to comply with, the statutory provisions set forth in paragraph 14, above, as to the '937 patent.

17. By filing the ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of its proposed famciclovir 125 mg, 250 mg and 500 mg tablets before the expiration of the '937 patent, Teva USA has committed an act of infringement under 35 U.S.C. § 271(e)(2). Further, the commercial manufacture, use, offer for sale, sale and/or importation of the generic famciclovir 125 mg, 250 mg and 500 mg tablets for which Teva USA seeks approval in its ANDA will also infringe one or more claims of the '937 patent.

18. On information and belief, if Teva USA's famciclovir 125 mg, 250 mg and 500 mg tablets are approved by the FDA and sold, they will be dispensed and used for all the purposes for which Famvir® tablets are indicated in Novartis' Famvir® product label. Those uses will constitute direct infringement of one or more of the method claims of the '937 patent. On information and belief, such uses will occur at the active behest of Teva USA and with their intent, knowledge and encouragement, and

Teva USA's activities will induce infringement of the '937 patent under 35 U.S.C. § 271(b).

19. Novartis is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of any approval of the aforementioned ANDA, relating to Teva USA's famciclovir 125 mg, 250 mg and 500 mg tablets, shall be a date which is not earlier than September 21, 2010, the current expiration date of the '937 patent, or any later date of exclusivity to which Novartis is or becomes entitled. Further, Novartis is entitled to an award of damages for any commercial sale or use of famciclovir 125 mg, 250 mg and 500 mg tablets, and any act committed by Teva USA with respect to the subject matter claimed in the '937 patent, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

20. On information and belief, when Teva filed its ANDA, it was aware of the '937 patent and was aware that the filing of its ANDA with the request for its approval prior to the expiration of the '937 patent was an act of infringement of this patent. On information and belief, Teva was aware that it had the obligations to make a good faith evaluation and have a reasonable belief that the patent for which it is seeking approval is invalid, before submitting its Paragraph IV certification to the FDA representing that the '937 patent was invalid, and to provide detailed reasons supporting that assertion in its Notice Letter, but Teva USA failed to make that evaluation or provide the required detailed factual and legal bases in its Notice Letter.

21. This is an exceptional case and Novartis is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

- A. Judgment that Teva USA has infringed one or more claims of the '937 patent by filing the aforesaid ANDA relating to Teva USA's famciclovir 125 mg, 250 mg and 500 mg tablets;
- B. Judgment that Teva USA has not complied with the requirements of 21 U.S.C. § 355(j)(2)(A)(vii)(IV), 21 U.S.C. § 355(j)(2)(B)(iv)(II), 21 C.F.R. § 314.94 and 21 C.F.R. § 314.95;
- C. A permanent injunction restraining and enjoining Teva USA and its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of famciclovir 125 mg, 250 mg and 500 mg tablets as claimed in the '937 patent;
- D. An order that the effective date of any approval of the aforementioned ANDA relating to Teva USA's famciclovir 125 mg, 250 mg and 500 mg tablets be a date which is not earlier than the expiration of the '937 patent, or any later date of exclusivity to which Novartis is or becomes entitled;
- E. Damages from Teva USA for any commercial activity constituting infringement of the '937 patent;

F. This is an exceptional case under 35 U.S.C. § 285, and Plaintiffs are entitled to the costs and reasonable attorney fees in this action; and

G. Such other and further relief as the Court may deem just and proper.

Dated: April 8, 2005

By: 

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